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before the Committee on Government Reform
United States House of Representatives
May 5, 2005

Mr. Chairman, Congressman Waxman, members of the Committee, I am Dennis Erb. I am responsible for Merck's interactions with pharmaceutical regulatory agencies around the world including the U.S. FDA. I am pleased to be able to discuss with you the important issue of the safety of FDA-approved drugs.

We appreciate the Committee's attention to this important matter. I hope that today, by discussing with you Merck's actions to study Vioxx following its approval, we can assist the Committee in understanding the role of post-approval clinical trials. It was through such trials that Merck diligently pursued information to further clarify the benefits and risks of Vioxx.

Our original application to the FDA for Vioxx included data from many studies involving approximately 10,000 patients. These studies compared the effects of Vioxx to other nonsteroidal anti-inflammatory medicines or NSAIDs and to placebo and included studies of patients who had been on Vioxx for longer than one year. The FDA and an independent advisory panel agreed that Vioxx was safe and effective when used in accordance with its prescribing information. FDA approved Vioxx in May of 1999.

Once approved, we continued to study Vioxx. Consistent with our history of scientific excellence, Merck initiated long-term, post-approval trials to investigate new uses for Vioxx and to further clarify its safety profile. We conducted many, large, post-approval trials for Vioxx with extensive input from the FDA. In fact, since submitting its original application, Merck has completed approximately 70 clinical trials on Vioxx involving more than 40,000 patients.

In one of those large trials – known as VIGOR – there was a higher incidence of cardiovascular thrombotic events in patients taking Vioxx compared to the NSAID naproxen. This result stood in contrast to our other data on Vioxx. In a pooled analysis of the clinical trials submitted for FDA approval, there were similar rates of cardiovascular thrombotic events between Vioxx and placebo, and between Vioxx and NSAIDs other than naproxen. Further, in two large on-going placebo-controlled trials, we found no difference in the rates of cardiovascular thrombotic events between Vioxx and placebo. These data led us to conclude that the difference in the cardiovascular event rates in VIGOR resulted from the anti-platelet effect of naproxen.

We promptly disclosed the results of this clinical trial and our interpretation of it to the FDA, physicians, the scientific community and the media. The cardiovascular results of VIGOR were widely reported and discussed at the time. We worked diligently with the FDA to review the data and develop revised prescribing information. And we also recognized the value and interest in obtaining additional cardiovascular safety data on Vioxx and we undertook additional clinical trials to do so.

We believed wholeheartedly in the safety of Vioxx and that Vioxx was an important treatment option for physicians and their patients. The labeling for NSAIDs has, for a number of years, included a warning about serious, and potentially fatal, gastrointestinal events. Vioxx was the only approved NSAID demonstrated to reduce the risk of serious gastrointestinal side effects compared to those on other NSAIDs. This was an important benefit for many who suffered from the pain of arthritis and other conditions.

On a personal level, I believed in the value that Vioxx provided to patients. My own father was a regular user of Vioxx until we voluntarily withdrew it from the market.

Mr. Chairman, in the seven months since that withdrawal, there have been many questions, and much discussion about the evidence of the safety of Vioxx. Yet, while Vioxx was on the market, the combined analysis of our controlled clinical trials demonstrated no increased risk of cardiovascular thrombotic events for patients taking Vioxx compared to patients taking placebo or NSAIDs other than naproxen.

Merck continued to conduct post-approval trials of Vioxx. In one of those – the APPROVe trial – there was an increased risk of confirmed cardiovascular events beginning after 18 months of continuous daily treatment in patients taking Vioxx compared to those taking placebo. Given the questions raised by the data and the availability of alternative therapies, we decided that withdrawing the medicine was the responsible course to take.

Today, Mr. Chairman, we know that the science has continued to evolve and new data on some of the alternative therapies to Vioxx have become available. These data were publicly reviewed by a special Advisory Committee in February. Both that Committee and the FDA have concluded that the increased cardiovascular risk seen in the APPROVe trial is shared by other COX-2 inhibitors. FDA also concluded that all NSAIDs should have a cardiovascular risk warning.

Given the unique benefits of Vioxx, Merck is considering these new data and will discuss their implications for Vioxx with the FDA and other regulatory authorities around the world.

In conclusion, Mr. Chairman, throughout Merck's history, it has been our rigorous adherence to scientific investigation, openness and integrity that has enabled us to bring new medicines to people who need them. We believe Merck acted appropriately and responsibly to extensively study Vioxx after it was approved for marketing to gain more clinical information about the medicine. And we promptly disclosed the results of these studies to the FDA, physicians, the scientific community and the media.

I will be pleased to respond to your questions.